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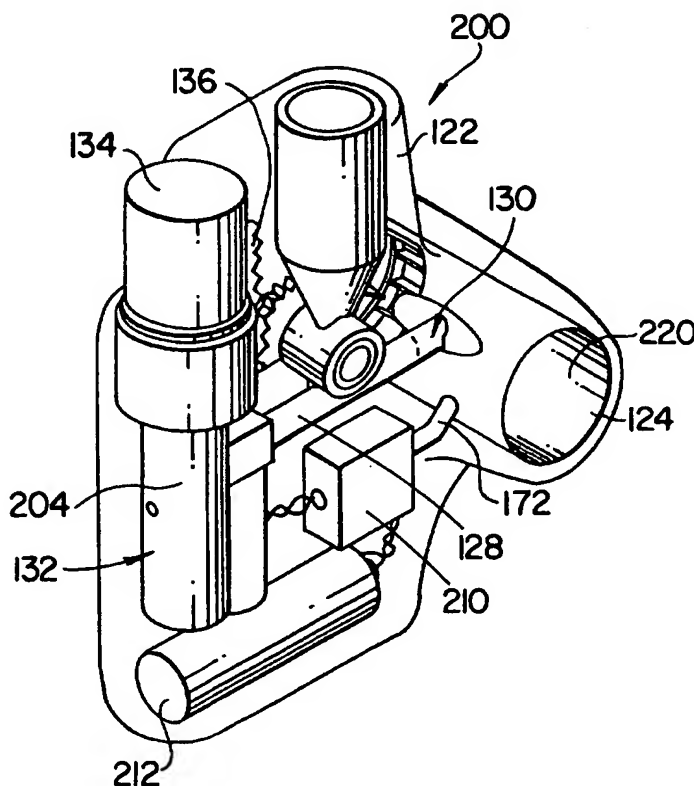
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| (71) Applicant: | DURA PHARMACEUTICALS, INC.
[US/US]; 7475 Lusk Boulevard, San Diego, CA 92121-4204 (US). | |
| (72) Inventors: | NODELMAN, Vladislav ; 7475 Lusk Blvd., San Diego, CA 92121 (US). GIESCHEN, Andrew, W. ; | |
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[Continued on next page]

- (54) Title:** COMPRESSED GAS DRY POWDER INHALER



- (57) Abstract:** A dry powder inhaler has a dispersion tube extending from a compressed air source to a mouthpiece. A dose of dry powder is introduced into the dispersion tube. Upon inhalation on the mouthpiece, a burst or bolus of compressed air is released into the dispersion tube, dispersing the powder and carrying the powder out through the mouthpiece. The dispersed particles are decelerated and inhaled in an inspiratory-flow rate independent manner, and with minimal wall losses. Respirable pharmaceuticals are delivered into the lung, inexpensively, efficiently, consistently and with low losses.

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DESCRIPTION

COMPRESSED GAS DRY POWDER INHALER

5 BACKGROUND OF THE INVENTION

The field of the invention is dry powder inhalers.

Dry powder inhalers have been used for many years to deliver doses of pharmaceutical substances, in form of dry powders, to patients. Usually, an individual dose of a dry powder is deposited into a chamber near a mouthpiece on the inhaler. When
10 the patient inhales on the mouthpiece, air moves through the inhaler. The dry powder is entrained in the moving air. The entrained powder and air is inhaled by the patient. Depending on the dry powder inhaler design, powder formulation, and inhalation characteristics, varying amounts of the powder will be deposited into the patient's deep lung regions.

15 In many dry powder inhalers, the energy required for dispersing the dry powder and entraining the dry powder into the air is derived from the patient's inspiratory force. In these types of inhalers, the efficiency or level of dispersion depends directly on the inspiratory force or work of the patient in inhaling. Consequently, the dose actually received by the patient can vary widely. For example, children, or patients with lung
20 conditions that largely prevent forceful inhalation, may not receive a full dose as readily as other patients. Consequently, the patient's medical treatment via the dry powder pharmaceutical may be degraded.

Some dry powder inhalers intend to overcome this disadvantage by providing mechanical, electrical, pneumatic, etc., energy to help disperse the powder. However,
25 many of these dry powder inhalers, using alternate powder dispersion techniques, have other disadvantages. Some require complex components and designs. Others do not fully achieve efficient powder dispersion, due to the dispersion mechanism.

Metered dose inhalers, which have long been used to deliver a variety of pharmaceuticals, largely avoid the difficulties in dispersing the pharmaceutical powder,
30 because the powder is contained within a pressurized container. The dispersion energy is produced by the rapid expansion of the propellant. However, metered dose inhalers require significant coordination between release of a dose and the patient's inspiration, and

the aerosol is presented to the patient with a high forward velocity. This results in significant loss of particles in the throat and upper airways. In addition, many metered dose inhalers require propellant gases which are damaging to the environment.

Accordingly, there remains a need for an improved dry powder inhaler.

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SUMMARY OF THE INVENTION

A surprisingly small volume of rapidly moving gas disperses or aerosolizes a relatively large amount of powder, because the gas and powder are confined to a relatively long and narrow enclosed geometry enclosure, such as a tube.

10 In a first aspect of the invention, a dry powder inhaler has a source for providing a rapidly moving gas, such as a compressed gas source, and a mouthpiece, connected at least indirectly to a dispersion conduit or tube. A powder port extends into the dispersion tube between the compressed gas source and the mouthpiece, for delivering a dose of dry powder into the dispersion tube. Powder is introduced into the dispersion tube prior to the
15 release of compressed gas. When a user inhales on the mouthpiece, or presses a button, a small burst of compressed gas is released into the dispersion tube. The rapidly moving expanding gas disperses the powder in the dispersion tube and carries it to the mouthpiece. Preferably, the speed of the expanding gas and entrained particles is reduced before, or at, the mouthpiece. The compressed gas may be air or another gas. Air is generally
20 preferred. The terms air and gas are used interchangeably, unless otherwise specified.

In a second aspect of the invention, air is compressed within the inhaler by movement of a loading button. The button drives an air pump which charges a compressed air reservoir. Inhalation at the mouthpiece is detected via a vacuum switch, which opens a valve to release compressed air into the dispersion tube when a user inhales
25 on the mouthpiece.

In a third aspect of the invention, rapid air flow is generated within the inhaler by movement of a button which compresses a spring. Upon inhalation by a user, the compressed spring is released, and drives a piston in a cylinder, causing a rapid flow of expanding air through the dispersion tube.

30 In a fourth aspect of the invention, movement of a loading button on the inhaler moves a dose of dry powder from a single dose or multiple dose storage container into the dispersion tube. Movement of the button also compresses air.

In a fifth aspect of the invention, the compressed air is decelerated via counterflow compressed air, or inspiratory air. Alternatively, the compressed air carrying the dry powder may be decelerated by impinging against a wall, by changing direction, or by moving through a diffuser.

5 Other objects and advantages will appear below. The invention resides not only in the combinations described above, but also in subcombinations of the foregoing features, elements and steps.

BRIEF DESCRIPTION OF THE DRAWINGS

10 In the drawings, wherein the same reference number indicates the same element, throughout the several views:

Fig. 1 is a cross section of an aerosolizer for use in a dry powder inhaler;

Fig. 2 is a plan view in part section of the aerosolizer of Fig. 1;

Fig. 3 is a section view of a first alternative aerosolizer;

15 Fig. 4 is a section view of a second alternative aerosolizer;

Fig. 5 is a plan view in part section of a third alternative aerosolizer;

Figs. 6 and 7 show alternative mouthpiece chamber shapes for the aerosolizer shown in Fig. 5;

Figs. 8, 9 and 10 are section views of additional alternative aerosolizer designs;

20 Fig. 11 is a schematic section view of an aerosolizer used in the examples described below;

Fig. 12 is a perspective view of an inhaler having an aerosolizer as shown in Figs. 1-11;

Fig. 13 is a side section view of the inhaler shown in Fig. 12;

25 Fig. 14 is a top section view of the inhaler shown in Fig. 12;

Fig. 15 is a perspective view of another inhaler having an aerosolizer as shown in Figs. 1-11;

Fig. 16 is a side section view of the inhaler shown in Fig. 15;

Fig. 17 is a top section view of the inhaler shown in Fig. 16;

30 Fig. 18 is a perspective view of another inhaler having an aerosolizer as shown in Figs. 1-11;

Fig. 19 is a perspective view of another such inhaler;

Fig. 20 is a side section view of the inhaler shown in Fig. 19;

Fig. 21 is a front section of the inhaler shown in Fig. 19; and

Fig. 22 is a plan view of the inhaler shown in Fig. 19.

Various of the elements shown in the different embodiments described above may
5 of course, be used alone, or in combination with features of the other embodiments, as will
be apparent to persons skilled in the art.

DETAILED DESCRIPTION

Powder is dispersed by shear forces induced within a dispersion conduit or tube by
10 a rapidly moving gas. The shear force is highest near the conduit wall and decreases to a
minimum value at the center of the conduit. For a given gas ejection pressure and ejected
gas volume, the mean shear force within the conduit is inversely proportional to the cross-
sectional area of the conduit. Therefore, the dispersion efficiency increases with
decreasing conduit cross-section area. However, the conduit cross-section area must not
15 be so narrow as to induce the powder to form a plug, thus clogging the conduit. While
release of a gas from a compressed gas source is a convenient way for providing a rapidly
moving gas, other techniques for producing a rapidly moving gas may also be used.

For a given gas ejection pressure and ejected gas volume, the duration of time
during which the powder is subjected to the shear forces within the dispersion conduit is
20 proportional to the volume of the conduit. If the conduit is too short, or too narrow,
powder is ejected before all potential aerosolization has occurred. If the conduit is too
long, or too wide, the gas does not provide sufficient momentum for the powder to exit the
conduit. Therefore, for a given gas ejection pressure and ejected gas volume, there is a
combination of conduit length and cross-sectional area which provide maximum
25 aerosolization.

Fig. 1 is a section view of an aerosolizer 20 having a dispersion conduit 28, a
deceleration gas inlet 26 positioned coaxially with the dispersion conduit 28, a dilution gas
inlet 84 and a mouthpiece 24. Fig. 2 is a top view of the dispersion conduit 28,
deceleration gas inlet 26, and dilution gas inlet 84. Powder 65 is introduced into the
30 dispersion conduit 28. Upon inhalation, a bolus of compressed air from a compressed air
source 32, is rapidly injected into the conduit 28 and traverses the conduit, entraining and
dispersing the powder. Inhaled air enters the mouthpiece 24 through the dilution gas inlet

84 and through the deceleration gas inlet 26. The ejected air-powder bolus collides with the deceleration air jet in the mouthpiece and is rapidly decelerated. The powder is then directed towards the mouth by the dilution air flow.

Fig. 3 shows an alternative embodiment 31 with the deceleration gas inlet 26 also
5 connected to the compressed gas source 32. Upon inhalation, a bolus of compressed gas is rapidly injected into the dispersion conduit 28 and traverses the conduit 28, entraining and dispersing the powder 65. At the same time, another bolus of compressed air is ejected into the deceleration gas inlet 26. The ejected gas-powder bolus collides with the deceleration gas bolus in the mouthpiece chamber 25 and is rapidly decelerated. The
10 powder is then directed into the mouthpiece 24 and towards the mouth by the dilution gas. A second powder 67 may be placed into the deceleration gas inlet 26 so that two powders are simultaneously presented to the patient during inhalation. In this aerosolizer 31, the two gas-powder boluses collide and decelerate in the mouthpiece chamber 25.

In another aerosolizer embodiment 41, as shown in Fig. 4, the deceleration gas
15 inlet is replaced by a wall 43. The ejected gas-powder bolus collides with the wall in the mouthpiece chamber 25 and is rapidly decelerated. The powder is then directed into the mouthpiece 24 and towards the mouth by the dilution gas.

In another aerosolizer embodiment 51, as shown in plan view in Fig. 5, two dispersion conduits 28 and 53 and two deceleration gas inlets 26 and 55 are positioned
20 coaxially with each of the two dispersion conduits. Powder 65 and 67 is introduced into each dispersion conduit. Upon inhalation, a bolus of compressed air is rapidly injected into the first conduit 28 and traverses the conduit, entraining and dispersing the powder 65. Inhaled air enters the mouthpiece chamber 25 through the dilution air inlet and through the deceleration air inlets 26 and 55. The ejected air-powder bolus collides with
25 the deceleration air jet in the mouthpiece chamber 25 and is rapidly decelerated. The powder is then directed into the mouthpiece 24 and towards the mouth by the dilution air. Shortly thereafter, powder placed in the second dispersion conduit 53 is introduced to the inhaled airflow in the same way. The angle between the dispersion conduit 53 and the deceleration inlet, θ , need not be 90°. Minimization of this angle results in a more
30 compact inhaler without affecting performance. The dilution air inlet 84 may also be at an angle (other than 90°) to the conduits or tubes 53.

Figs. 6 and 7 show top view of aerosolizers similar to aerosolizer 51, but modified

to show a rectangular mouthpiece chamber 61 and an elliptical mouthpiece chamber 71.

Another aerosolizer embodiment 81, as shown in Fig. 8 has a dispersion conduit 83, a dilution/deceleration gas inlet 84, and a mouthpiece 24. Powder is introduced to the dispersion conduit 83. Upon inhalation, a bolus of compress air is rapidly injected into the conduit 83 and traverses the conduit 83, entraining and dispersing the powder. Inhaled air enters the mouthpiece chamber 25 through the dilution gas inlet 84. The ejected gas-powder bolus collides with the dilution air in the mouthpiece chamber 25 and is rapidly decelerated. The aerosolized powder is then directed into the mouthpiece 24 and towards the mouth by the dilution air.

Fig. 9 shows an embodiment 91 similar to the design of Fig. 8, and including a second dispersion conduit 93. In this embodiment, since deceleration of the ejected gas-powder bolus is performed by the dilution air, the first powder 65 can be ejected before or after the second powder 67.

As shown in Fig. 10, in an embodiment 95, the outlet of the second dispersion conduit 93 may be in-line with the first dispersion conduit 83.

Fig. 11 shows a specific embodiment 97 of the aerosolizer of Fig. 1, with specific dimensions $\underline{A} = 0.24\text{cm}$; $\underline{B} = 2.54\text{cm}$; $\underline{C} = 2.51\text{cm}$; and $\underline{D} = 0.80\text{cm}$. In an aerosol performance study using the aerosolizer of Fig. 11, with a 1.76% albuterol sulfate-lactose blend, a 350 k Pa (30 psi), 10 msec, 2 ml air-bolus ejection produced an albuterol sulfate (AS) respirable fraction (RF) of approximately 45%. The holdup of albuterol sulfate and lactose in the dispersion conduit was less than 5%. These results were consistent for blend masses from 3 to 13 mg.

Turning now to Figs. 12-14, an inhaler 120 has a mouthpiece 124 formed on an inhaler housing 122. The internal mouthpiece walls taper conically outwardly towards the mouthpiece opening 129, forming a diffuser 125. The diffuser 125 extends from the mouthpiece opening 129 inwardly to a mouthpiece chamber 182.

An air inlet 126 formed in the housing 122, has converging walls forming a nozzle 127. The air inlet 126 intersects with, or joins into the mouthpiece chamber 182. Alternatively the air inlet 126 may have straight, non-converging walls 127A, as shown in dotted lines in Fig. 14. A dispersion tube 128 extends from a compressed air or gas source 132 into the mouthpiece chamber 182. The dispersion tube 128 and air inlet 126 are coaxial and on opposite sides of the mouthpiece chamber 182. A dilution air or chamber

inlet 184 also connects into the mouthpiece chamber 182, preferably through a laminar flow device 180, with the chamber inlet 184 coaxial with, and opposite from, the mouthpiece 124.

The dispersion tube 128, air inlet 126, mouthpiece 124 (or the mouthpiece walls
5 125) and the chamber inlet 184, together form an air flow path 130 through the housing 122. The dispersion tube (in any embodiment shown) preferably has a round cross section. However, the dispersion tube may have other cross-sectional shapes, such as square, rectangular, triangular, oval, D-shaped or star shaped. The dispersion tube may also be curved as shown in Figs. 8-10, or coiled or spiral, to reduce space requirements.
10 Nozzle sections may also be used, specifically just upstream from the powder port.

As best shown in Fig. 13, a preset or load button 134 has a rack section 136. Gear teeth on the rack section 136 engage corresponding gear teeth on a pinion section 156 attached to a drum 152. The drum is pivotably contained within a drum cylinder 154 within a powder storage chamber 150. The drum 152 is aligned with a powder port 158 in
15 the dispersion tube 128. A button return spring 138 biases the button 134 upwardly, or outwardly from the housing 122. A shaft 135 extending outwardly from the button 134 is aligned with a foot 145 of a piston 140 slidably contained within a cylinder 142. A ring seal 144 on the piston 140 slidably seals the piston 140 within the cylinder 142. A piston spring 146 between the piston foot 145 and an inside wall of the housing 122 urges the
20 piston 140 into the cylinder 142. The cylinder 142 connects into, or forms part of the dispersion tube 128. The button 134, piston spring 146, piston 140 and cylinder 142 together form a compressed air source 132.

Referring still to Fig. 13, a vacuum tube 172 extends from a location in the air flow path 130, at or near the mouthpiece 124, to a diaphragm 174. A pawl 176 attached to the
25 diaphragm 174 has a pawl latch 178 adapted to engage the piston foot 145, and hold it outwardly (or downwardly in Fig. 13) against the force exerted by the piston spring 146.

In use, the inhaler 120 is provided with multiple doses of pharmaceutical powder, stored in bulk, in the powder storage chamber 150, with the inhaler 120 intended to be discarded after the powder in the storage chamber 150 is used up. Alternatively, the
30 inhaler 120 can be adapted so that the housing 122 can be opened to replace the powder storage chamber 150. With the storage chamber 150 containing pharmaceutical powder, the user initially presses the button 134 down or into the housing 122. As this occurs, the

rack 136 drives the pinion sector 156 by about 180 degrees, inverting the dose cup 160 on the drum 152. As a result, a dose of powder 65 is moved in the dose cup 160 from the storage chamber 150 to the powder port 158. With the inhaler 120 held upright, the dose of powder falls out of the dose cup 160 and into the dispersion tube 128. As the drum 152 fits tightly within the drum cylinder 154, the powder port 158 remains effectively closed or sealed (regardless of the rotational position of the drum 152). Consequently, compressed air cannot flow out of the dispersion tube 128 through the powder port 158. In this way, pressing the button 134 down therefore delivers a single dose of powder from the storage chamber 150 into the dispersion tube 128.

10 Movement of the button 134 also moves the shaft 135 downwardly (as shown in Fig. 13), so that it pushes the piston foot 145 downwardly against the upward acting force of the piston spring 146. With the button 134 fully depressed, the pawl latch 178 on the pawl 176 latches onto the piston foot 145, holding it in the down position, as shown in dotted lines in Fig. 13.

15 The user then releases the button 134. The button 134 moves back up or outwardly into its original position, under the force of the button return spring 138. However, the piston foot 145 and piston 140 remain in the down position, held in place by the pawl latch 178.

The user then moves the inhaler 120 to the mouth and inhales on the mouthpiece 124. As this occurs, the pressure reduction at or near the mouthpiece 124, and at the diaphragm 174 via the vacuum tube 172 causes the diaphragm 174 to pull the pawl latch away from the piston foot 145. As the piston foot 145 is released, the piston spring 146 drives the piston 140 rapidly upwardly within the cylinder 142, creating a rapid burst or pulse of compressed air within the dispersion tube 128. The compressed air flows over the dose of powder 65 in the dispersion tube 128 below the powder port 158. The rapidly moving air entrains the powder 65, dispersing the powder and carrying it towards the mouthpiece 124.

As a result of the patient's inspiration, ambient air flows into the air inlet 126 and accelerates in the nozzle section 127. As the inlet 126 is coaxial with the dispersion tube 128, the inlet air impinges against the compressed air (and dispersed powder), moving in the opposite direction, at the mouthpiece chamber 182. This causes the rapidly moving compressed air to decelerate, allowing the compressed air/dispersed powder to change

direction and move outwardly through the mouthpiece 124. The diffuser 125 in the mouthpiece 124 further slows the compressed air and dispersed powder. The slowed compressed air, dispersed powder, and inlet air moves into the patient's mouth, throat, and lungs, to deliver the pharmaceutical powder into the lungs, for therapeutic, diagnostic, or prophylactic treatment. If necessary, the foregoing steps can be repeated to immediately deliver additional doses. Of course, other powder storage devices, such as blister disk, tapes, or strips, cassettes, or capsules may be used, in place of the bulk powder container shown in the Figures.

Turning to Figs. 15, 16, and 17, in another inhaler embodiment 200, the button 134 is directly connected to the piston 140 within a cylinder 142. The cylinder 142 is connected to a compressed air reservoir 204 through a transfer valve 206. The reservoir 204 connects to the dispersion tube 128 through a release valve 214. The vacuum tube 172 extends from the mouthpiece 124 to a vacuum switch 210. The vacuum switch 210 is electrically linked to a solenoid 208 which opens and closes the release valve 214. A battery 212 powers the solenoid 208, as controlled by the vacuum switch 210.

Referring to Fig. 17, a cylindrical mouthpiece tube 220 extends through the mouthpiece 124. A breath-driven turbine 224 is provided at the back end of the mouthpiece tube 220 adjacent to an air inlet 222, formed by the open back end of the mouthpiece tube 220. A laminar flow control device 226 and a centrifugal particle trap 228 are advantageously provided in the mouthpiece tube 220, in front of the turbine 224. The turbine 224 is rotatably supported on a diverter 230 centered in the mouthpiece tube 220 by struts extending radially inwardly from the mouthpiece tube 220. The dispersion tube 128 extends into the mouthpiece tube 220 and has an air flow path that makes a right angle turn. Accordingly, the outlet 234 of the dispersion tube 128 is facing the diverter cone 230. An aerodynamic housing 236 is formed around the outlet 234.

In use, the inhaler 200 is provided with one or more doses of a dry powder pharmaceutical to be inhaled by the user, as described above for the inhaler shown in Figs. 12-14. The user presses the button 134. This drives the piston 140 into the cylinder 142. The air within the cylinder 142 flows through the one way transfer valve 206 and into the compressed air reservoir 204. The volume of the reservoir 204 is substantially smaller than the volume of the cylinder 142. Consequently, a charge of compressed air is generated within the reservoir 204, with a single downward movement of the button 134.

The release valve 214 is closed. Consequently, the compressed air within the reservoir 204 is contained, and cannot move into the dispersion tube 128. The movement of the actuation button 134 also delivers a dose of powder 65 into the dispersion tube 128, as described above.

5 The user then inhales on the mouthpiece 124. The pressure drop in the mouthpiece 124 is sensed by the vacuum switch 210, which is connected to the mouthpiece area by the vacuum tube 172. The vacuum switch 210 closes as a threshold of the user's inhalation is detected. The vacuum switch 210 (or the diaphragm in Figs. 12-14) is selected so that when inspiratory flow rate reaches a predetermined value, the solenoid 208 extends,
10 opening the release valve 214 and releasing the compressed air. The compressed air in the reservoir 204 then rushes out into the dispersion tube, entraining and dispersing the powder 65. The air/powder mixture moves down the dispersion tube, makes a right angle bend at the outlet/nozzle housing 236 and then moves out of the outlet 234 into the mouthpiece tube 220. The turbine 224 induces a flow that preferentially segregates larger
15 particles from smaller ones.

As the patient is inhaling on the mouthpiece 124, inlet air is drawn into the mouthpiece tube 220 through the air inlet 222, and moves in a direction opposite to the direction of the compressed air/powder moving out of the outlet 234. The diverter cone 230 causes the compressed air and powder exiting the outlet 234 to move radially
20 outwardly towards the cylindrical walls of the mouthpiece tube 220. This movement, along with the inlet air moving in the opposite direction causes the compressed air and powder to change direction and flow forwardly in the mouthpiece tube 220, towards the mouthpiece 124. The decelerated compressed air, dispersed powder, and inlet air, is inhaled by the patient.

25 As shown in Fig. 18, in another embodiment 280, a prefilled compressed air or gas cartridge 282 is provided, in place of the compressed air source 132 shown in Figs. 12-17. The compressed air cartridge 282 may be capable of providing hundreds of doses. A release valve 214 releases a predetermined amount of compressed air from the cartridge 282, when a user inhales on the mouthpiece 124. The cartridge 282 may be replaced
30 through a door 285 in the housing 122. The inhaler 280 otherwise shares the features shown and described above.

In the inhaler designs shown above, the dispersion tube 128 typically has a lumen

or an inside diameter of from about 0.5 to 8 millimeters, preferably about 1 to 5 millimeters, and more preferably 1.5 to 3.0 millimeters. The dispersion tube length is at least 1 centimeter long and preferably 2 to 6 centimeters. The volume of compressed air released with each actuation ranges from 1-5 ml, and preferably about 2 ml. (with a 2.5
5 millimeter inside diameter dispersion tube). As this volume is so small, it is easily generated via the finger actuation described above. The release of compressed air into the dispersion tube takes 2-6 milliseconds, and the air-powder bolus exits the dispersion tube 5-50 milliseconds following the release of compressed air. The velocity of the air through the dispersion tube is preferably from about 5-25% of sonic velocity, and typically about
10 10%, with a 10 millisecond duration.

The shear force within a dispersion conduit of any cross-sectional geometry can be calculated. Therefore, a dispersion conduit of any cross-sectional area can be used to disperse the powder efficiently, provided that the shear force within the conduit is similar to or greater than the shear force in the preferred cylindrical conduit, such as they
15 conduits described above.

As the drug powder is dispersed and moved out of the dispersion tube 128 within about 25 milliseconds of the user reaching a preselected inspiratory flow rate, the inhalers provide the pharmaceutical powder to the user early in the inspiration cycle, therefore increasing the amount of pharmaceutical particles reaching the lower respiratory or deep
20 lung region, even at small tidal volumes. On the other hand, if treatment of the upper airways is necessary, the air-powder bolus may be released closer to the end of inhalation

The distance between the powder port 158 and mouthpiece chamber 182, and the distance between the compressed air source 132 and the powder port 158, are selected so that the compressed air and powder can move through the inhaler to the mouthpiece
25 chamber 182, preferably in less than 20 milliseconds. Consequently, these distances are minimized.

For delivery of pharmaceutical powder to the lungs, the volume of the ejected air bolus has to be small relative to the 1-3 liter lung volume of a typical patient. In addition, to ensure that the inspired pharmaceutical powder reaches the deep lung region, the
30 ejection must occur early in the inhalation sequence, and be sufficiently short relative to the typical 1-3 second inhalation duration. Accordingly, for use with inhalers having dispersion tube dimensions, as described above, ejection pressures of from 70-350 k Pa

(10-50 psi), and preferably from 175-245 kPa (25-35 psi) are used, along with release valve 214 opening durations of from 2-10 milliseconds. The characteristics of the mouthpiece chamber 25, dispersion tube 28, 53 and 83, dilution air inlet 84, deceleration air inlets 26 and 53, and the other features shown in Figs. 1-11 of course apply as well to the inhalers shown in Figs 12-22

Another embodiment 300 as shown in Figs. 19-22, is similar to the embodiment shown in Figs. 12-14, having a similar compressed air source 132, pawl 176 and pawl latch 178. However, in the inhaler 300 doses are provided in a coiled strip 304 of spaced apart blisters 305, contained within a magazine 302 of the inhaler housing 301. The strip 304 runs through a feed fixture 306 and onto a take up reel 308. The fixture 306 holds the strip in position in alignment over the powder port 158.

An advancing lever 316 on the outside of the inhaler housing is connected to drive gear 315 through a clutch 312. A return spring 317 urges the lever into an upright position. The drive gear is meshed with a feed rack 310 extending into the feed fixture 306. A blister breaker 314 is attached to the button 134 and is aligned over the fixture 306 and the powder port 158.

In place of the diaphragm 174 in the embodiment of Figs. 12-14, a release button 318 on the outside of the inhaler housing 301 is connected to the pawl latch 178 through a release link 320.

In use, the user pushes down on the advance lever 316. This turns the drive gear 315 and draws the feed rack 310 incrementally through the feed fixture 306, to move an unused blister 305 on the strip 304 into alignment over the powder port 158. Simultaneously, it advances the take up reel 308. After the next blister is aligned, the clutch 312 allows the lever 316 to move further without further moving the strip 304, by allowing the lever 316 to slip relative to the drive gear 315. The return spring 317 returns the lever to the up position, after the user releases it.

Next, the user pressed down on the button 134, setting the compressed air source 132, as described above in connection with Figs. 12-14. At the same time, the blister breaker on the button moves down and punctures, bursts, or shears out the bottom of the blister, allowing the dose of powder in the blister 305 to fall out into the dispersion tube 128.

The user then places the mouthpiece 124 into the mouth. However, unlike the

design shown in Figs 12-14, there is not diaphragm or other automatic release. Rather, the user, when ready, presses the release button 318. This movement of the button 318, through the linkage 320, pulls the pawl latch away from the piston foot 145, generating a rapid flow of air through the dispersion tube. Subsequent doses are delivered by repeating these steps until all blisters 305 on the strip 304 have been used. Then, the strip 304 or the inhaler 300 is replaced.

The release button 318, and the blister strip 304, as well as all of the other features described above in connection with Figs. 1-22, may of course be used individually and in various combinations and subcombinations. In addition to the bulk powder storage shown in Figs. 12-14, and the blister strip shown in Figs. 19-22, other powder storage techniques, such as cassettes, individual blisters, etc. may be used.

CLAIMS

1. A dry powder inhaler comprising:
a dispersion tube;
5 a powder port in the dispersion tube;
a gas source for providing a rapidly moving gas connected to the dispersion tube
on a first side of the powder port;
a mouthpiece connected to the dispersion tube on a second side of the powder port,
opposite to the first side; and
10 a release linked to the gas source.
2. The inhaler of claim 1 where the gas source comprises a volume of
compressed gas.
- 15 3. The inhaler of claim 2 with the compressed gas source comprises an air
pump.
4. The inhaler of claim 3 where the release is breath actuated, for releasing
compressed gas into the dispersion tube.
20
5. The inhaler of claim 1 further including an inlet joining into the dispersion
tube adjacent to the mouthpiece.
6. The inhaler of claim 1 with the dispersion tube having a round cross
25 section.
7. The inhaler of claim 1 further including a dose delivery system for
providing a dose of powder into the powder port.
- 30 8. The inhaler of claim 2 further including a mechanism for converting a
pressure change adjacent to the mouthpiece at least indirectly into a mechanical
movement, for releasing compressed air, upon inhalation on the mouthpiece.

9. The inhaler of claim 1 further including a mouthpiece chamber in the mouthpiece, with the dispersion tube, an inlet tube, connecting into the mouthpiece chamber.
- 5
10. The inhaler of claim 9 further including a diffuser in the mouthpiece connecting into a front side of the mouthpiece chamber, and a dilution flow inlet connecting into a back side of the mouthpiece chamber.
- 10
11. The inhaler of claim 8 wherein the mechanism comprises a diaphragm having a pawl latch engageable to the compressed air source, to cause the compressed air source to release compressed air into the dispersion tube, upon movement of the diaphragm, and a vacuum tube extending from the diaphragm to the mouthpiece.
- 15
12. The inhaler of claim 8 wherein the mechanism comprises a breath-actuated switch for actuating a solenoid attached to a release valve.
13. A method for dispersing a dose of a dry powder pharmaceutical so that it can be inhaled by a user, comprising the steps of:
- 20
- moving the dose of powder into a dispersion tube;
introducing a volume of rapidly moving air into the dispersion tube upon inhalation by the user; and
entraining the powder in the volume of rapidly moving air.
- 25
14. The method of claim 13 where the powder and air is decelerated, but not stopped, before it is inhaled.
15. The method of claim 13 where the deceleration step includes impinging ambient air against the entrained powder.
- 30
16. The method of claim 13 wherein the deceleration step comprises changing the direction of the entrained powder.

17. The method of claim 13 where the deceleration step includes flowing the entrained powder through a diffuser.

5

18. The method of claim 13 where the volume of rapidly moving air is provided by releasing air from a compressed air source.

19. The method of claim 18 further including the step of opening a port in the dispersion tube to move the dose of powder into the dispersion tube, and then closing the port, before releasing the burst of compressed air.

10

20. The method of claim 18 further including the step of pressing a button to create a reservoir of compressed gas.

15

21. The method of claim 18 where the burst of compressed gas is released only after the entire dose of powder is moved into the dispersion tube.

22. The method of claim 18 further including the steps of detecting inhalation and releasing compressed air into the dispersion tube, upon detection of inhalation.

20

23. The method of claim 18 further including the step of pressing a release button to release compressed gas into the dispersion tube.

24. The method of claim 13 further including the step of decelerating the entrained powder and air, before it is inhaled by the user.

25

25. The method of claim 13 where the volume of gas is 1-5ml.

26. The method of claim 13 where the tube has a diameter of 1-5mm.

27. The method of claim 13 wherein the gas moves through the dispersion tube is less than 20 milliseconds.

28. The method of claim 13 wherein the dispersion tube has a geometry which creates a shear force equal to the shear force of a round tube having a diameter of from 1-5mm.

30

29. The method of claim 28 where the volume of gas is from 1-5 ml and the gas passes through and exits the dispersion tube within 5-50 milliseconds of the initial movement of the gas.

30. A dry powder inhaler comprising:
5 a dispersion tube;
a powder entry port in the dispersion tube;
a gas accelerator connected to the dispersion tube on a first side of the powder entry port; and
a mouthpiece connected to the dispersion tube on a second side of the powder
10 entry port, opposite to the first side.

31. The inhaler of claim 30 where the gas accelerator comprises a piston slidably contained within a cylinder connecting to the dispersion tube.

32. The inhaler of claim 31 further including an inhaler housing containing the dispersion tube, the powder port entry, the gas accelerator, and the release, and with a
15 button on the outside of the housing joined to the piston.

33. The inhaler of claim 32 further including a spring urging the piston to move within the cylinder, and a release for holding the piston at a first position within the cylinder, and for releasing the piston, allowing the spring to move the piston to a second position within the cylinder, thereby causing a gas within the cylinder to flow out of the
20 cylinder and into the dispersion tube.

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Fig. 1

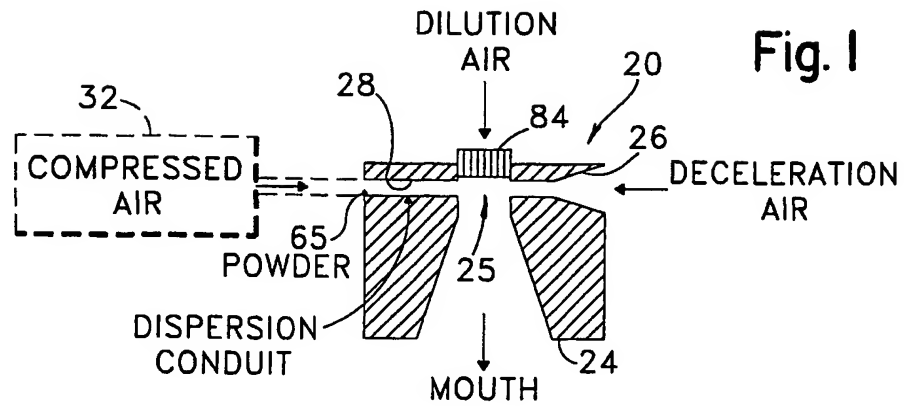


Fig. 2

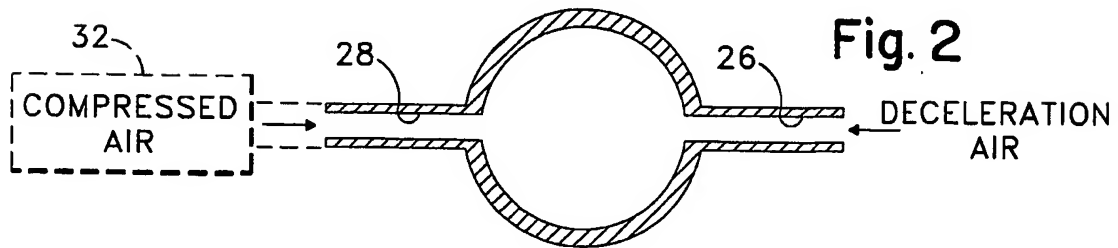


Fig. 3

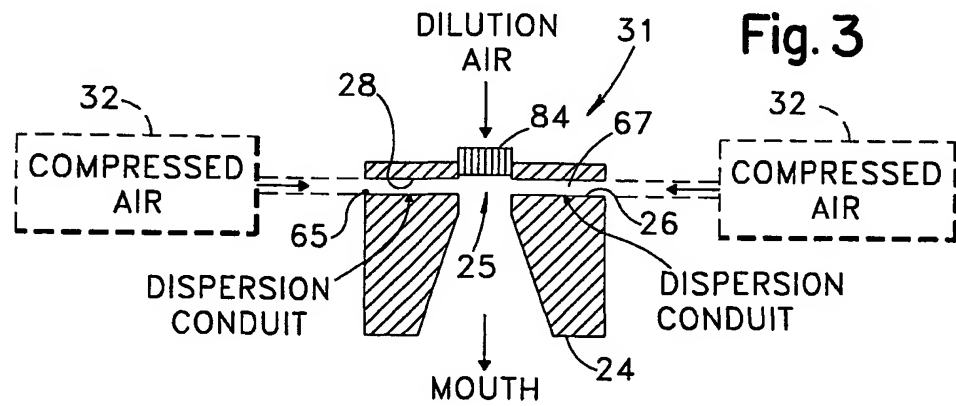
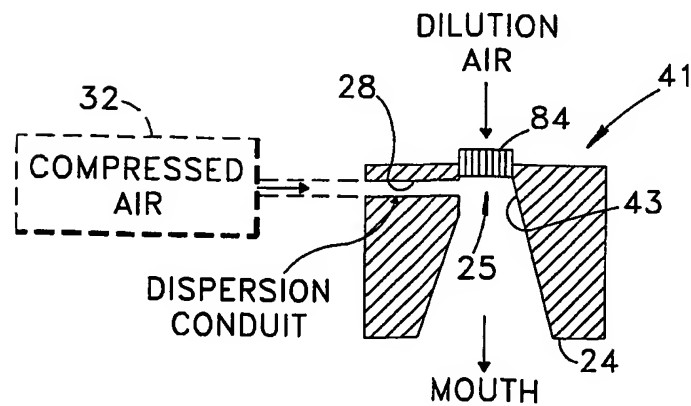


Fig. 4



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Fig. 5

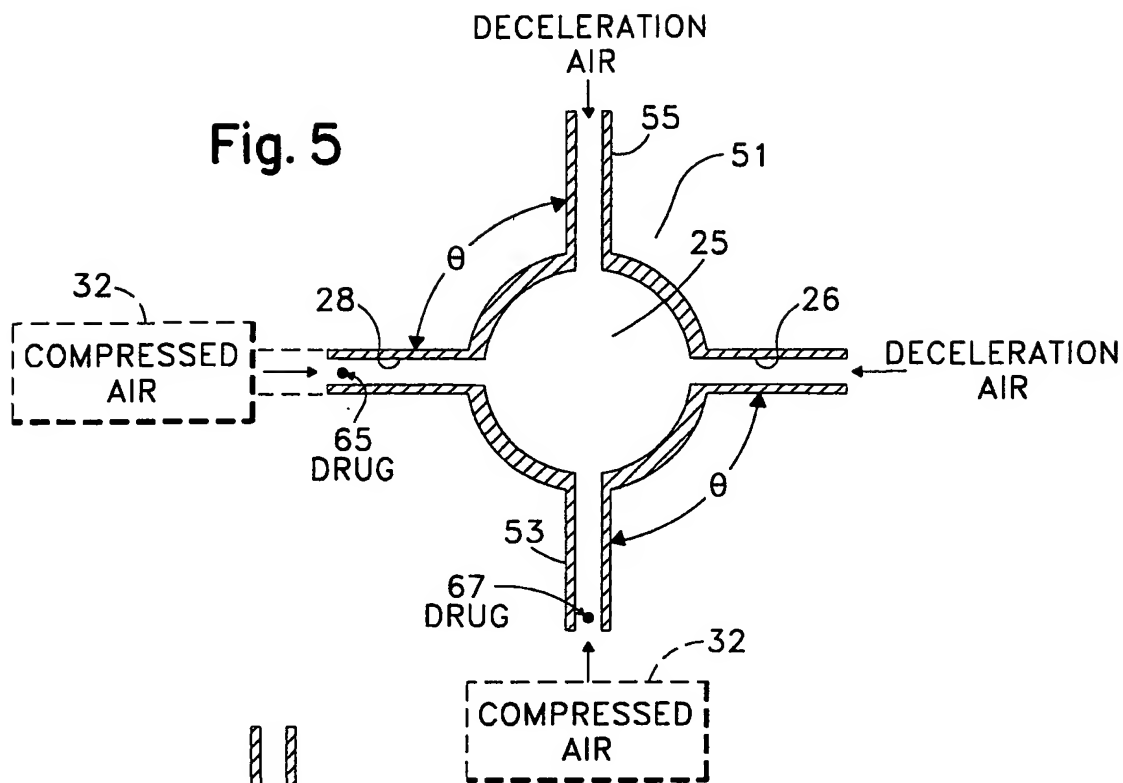


Fig. 6

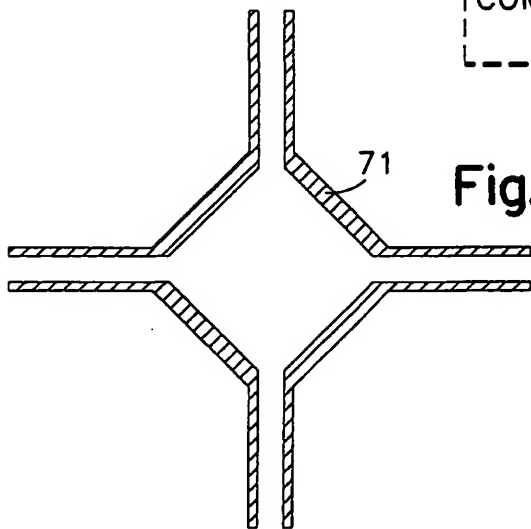
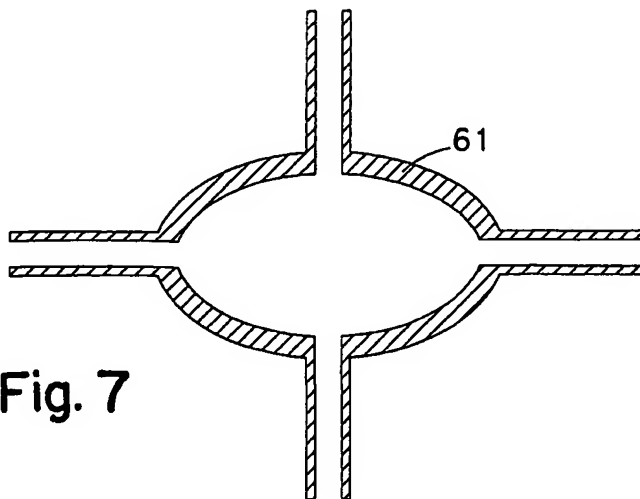


Fig. 7



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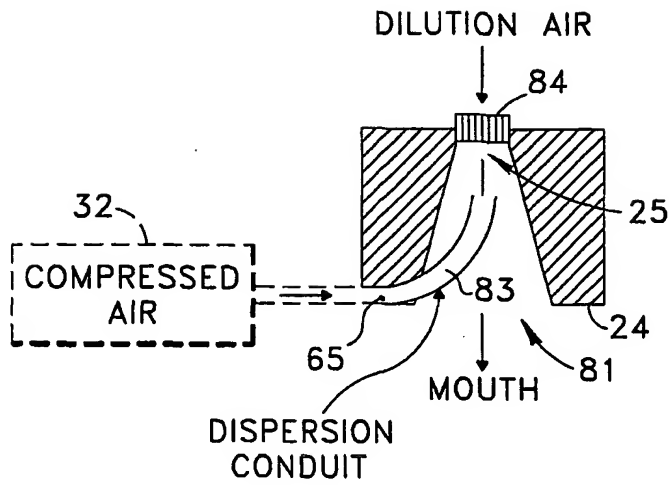


Fig. 8

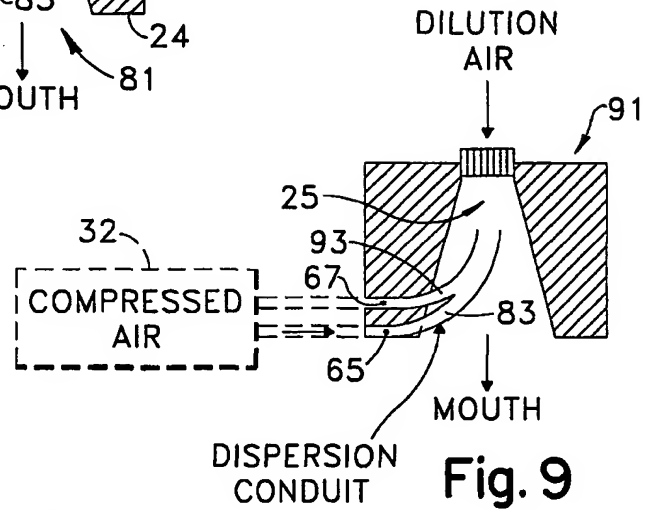


Fig. 9

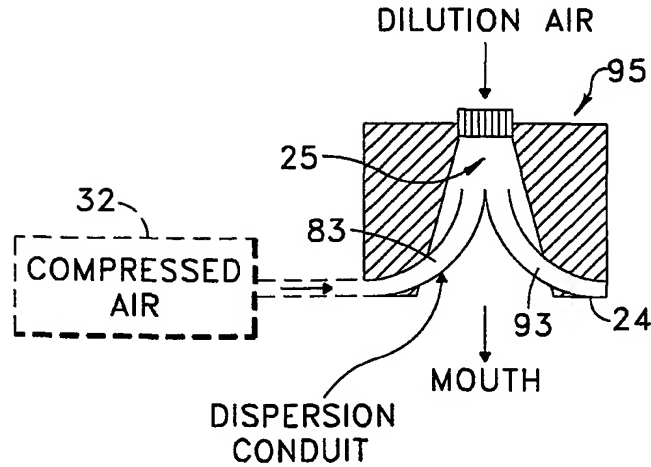


Fig. 10

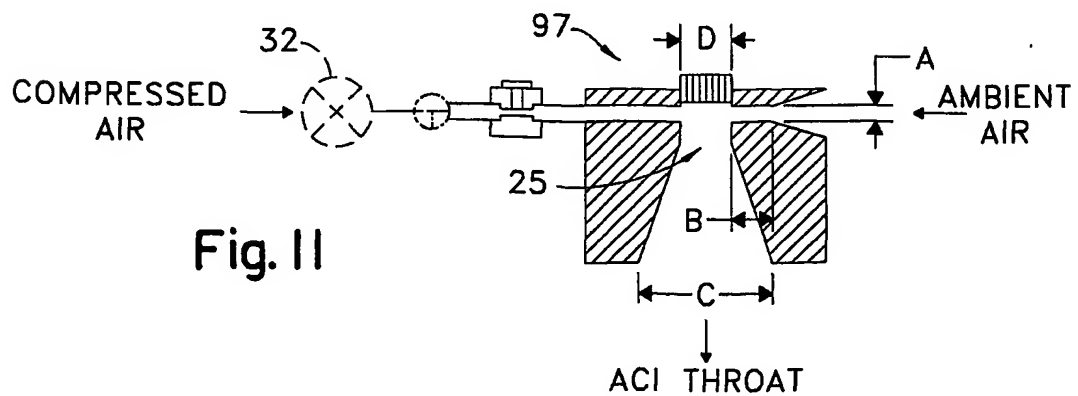


Fig. 11

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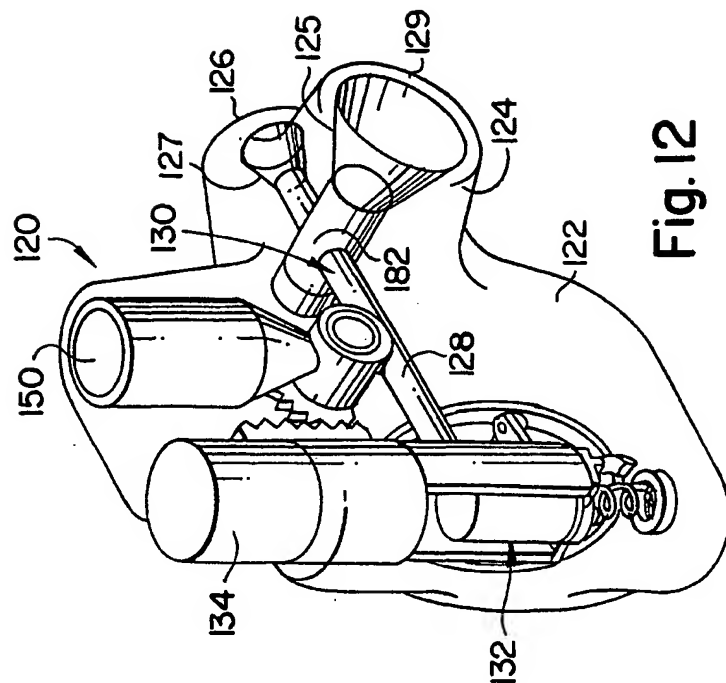


Fig. 12

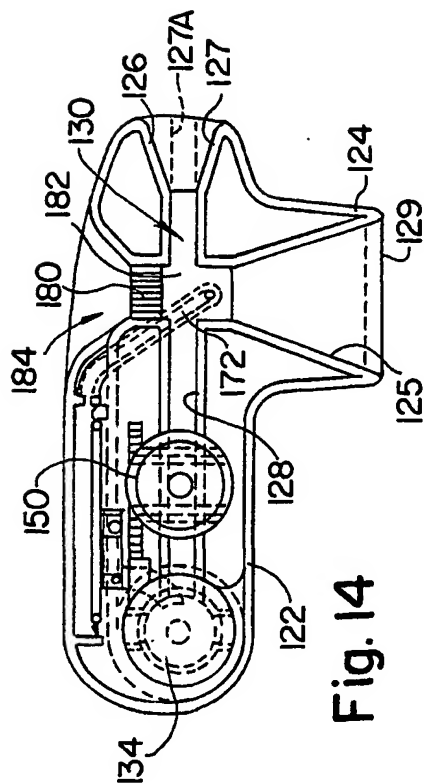


Fig. 14

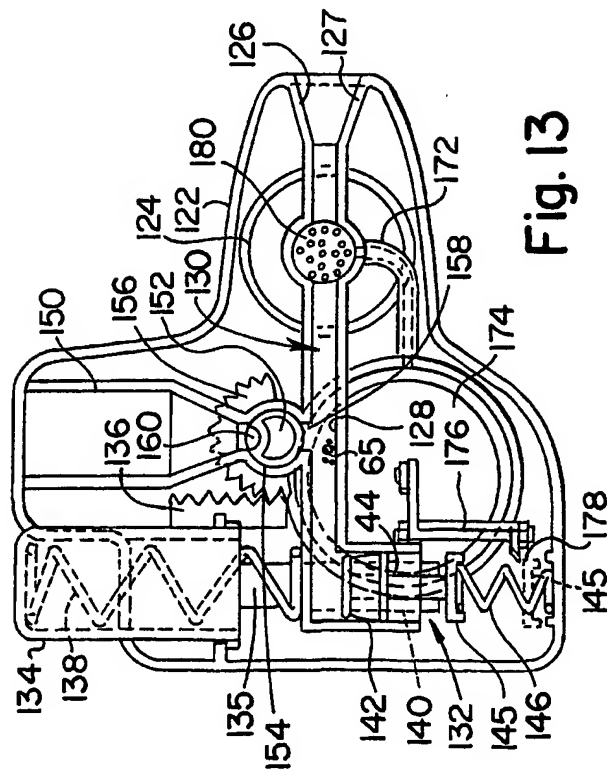
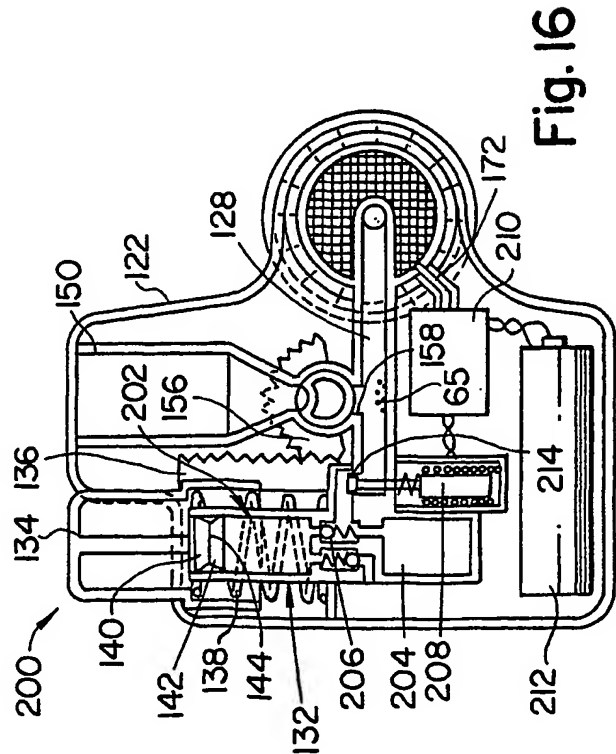
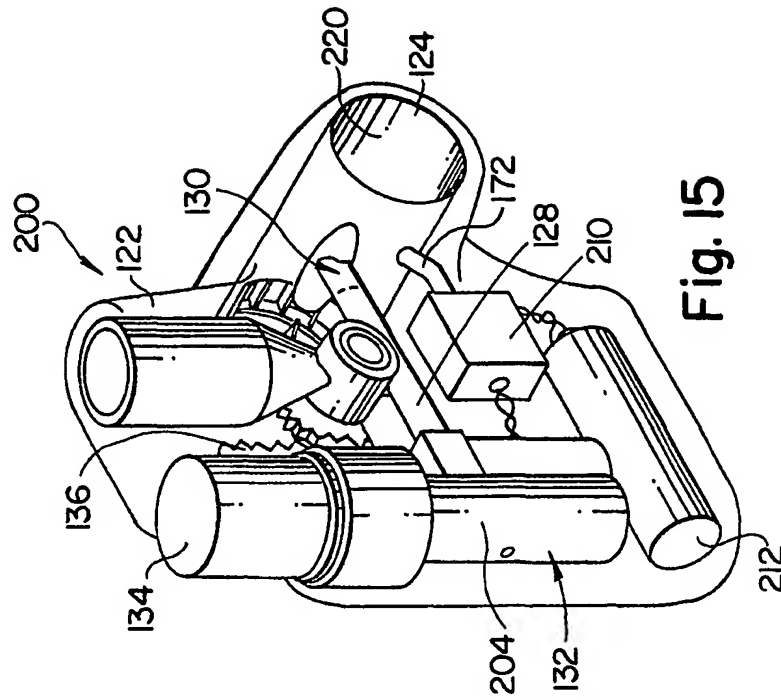
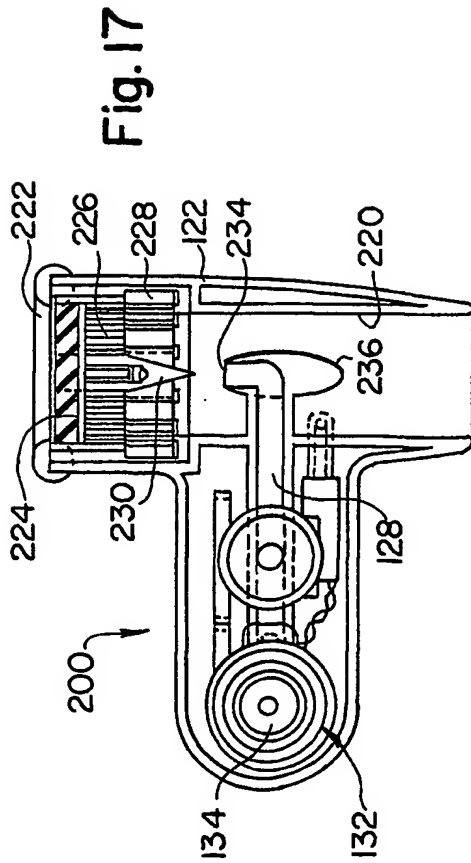
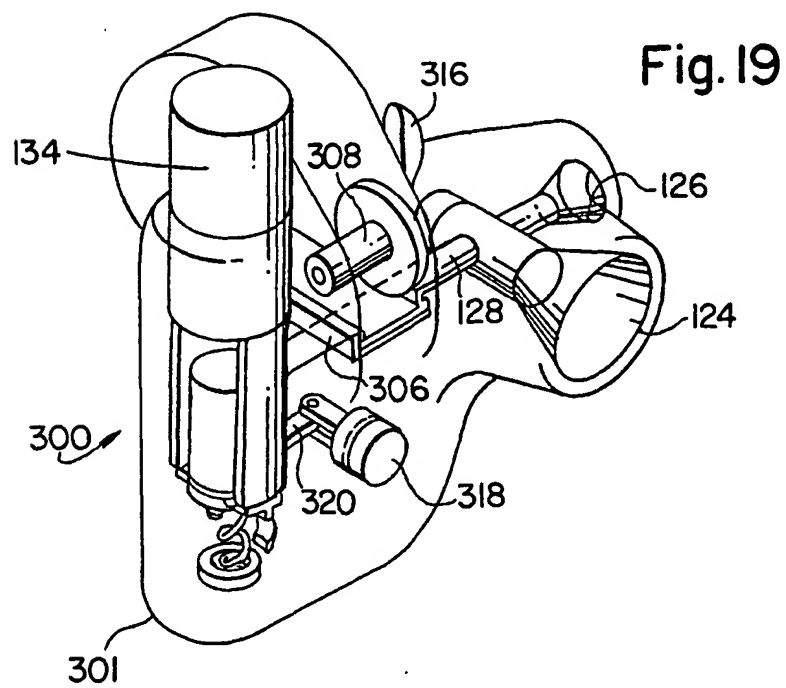
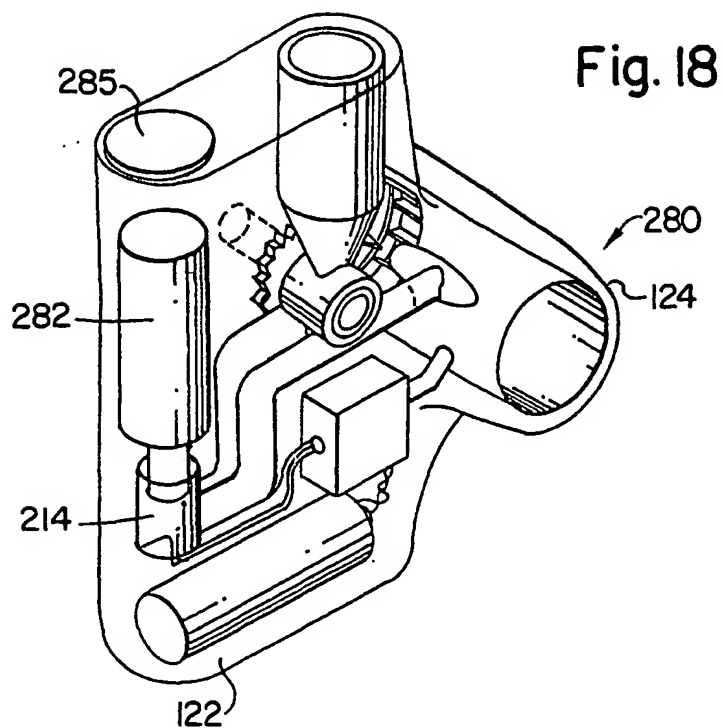


Fig. 13

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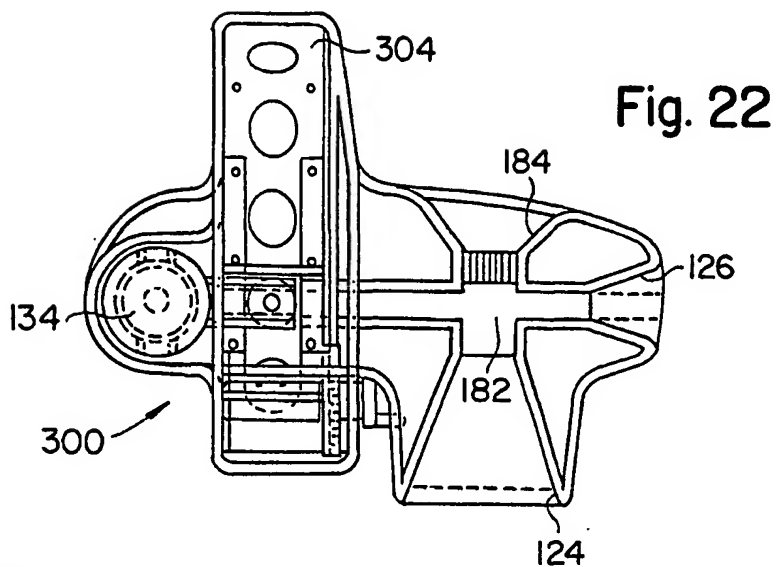


Fig. 22

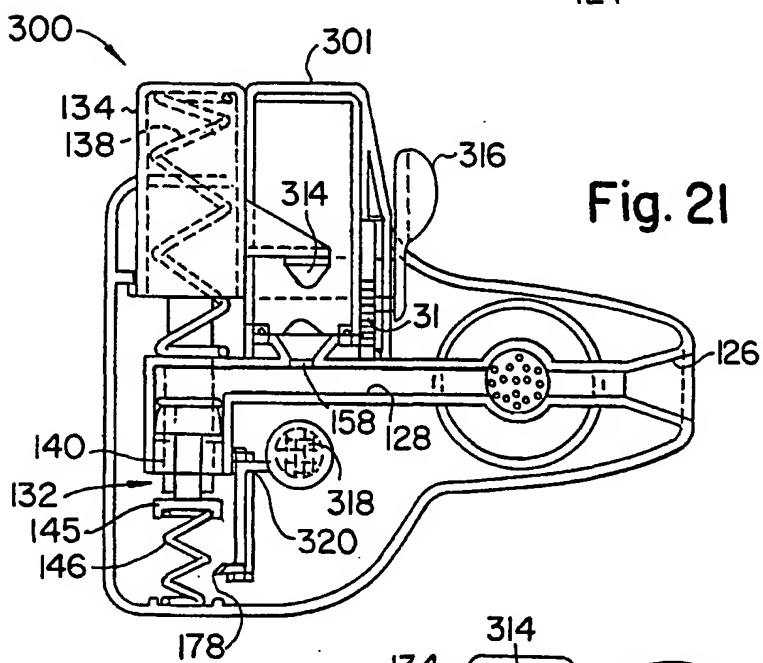


Fig. 21

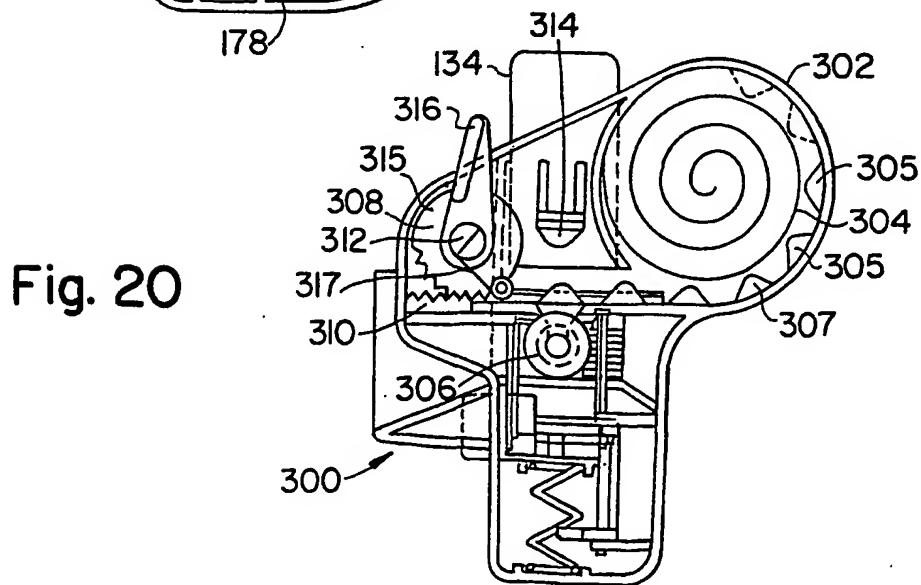


Fig. 20

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